Hawken Industries Inc.
Horizon Epikeratome Microkeratome
510(k) Submission

510(k) Summary

(1) Submitter Information

Name: Hawken Industries Inc.

Address: 26650 Renaissance Pkwy.
Suite 3
Cleveland, Ohio 44128

Telephone Number: 216-831-6782

Contact Person: Dr. George Myers
Medsys Inc.
377 Rt. 17 S
Hasbrouck Heights, NJ 07604
201-727-1703

Date Prepared: October 4, 2005

(2) Name of Device:
Trade Name: Horizon Epikeratome Microkeratome
Common Name: Disposable Microkeratome
Classification Name: Keratome, A-C powered

(3) Equivalent legally-marketed devices:

The predicate devices for the Horizon Epikeratome are Hawken Flapmaker, K981155, and the Norwood Abbey Centurion, K051486.

(4) Description

The device consists of a control console and disposable HORIZON EPIKERATOME™ microkeratome hand pieces. The control console contains a suction pump, electronics, and a flexible cable to actuate the disposable microkeratome. The basic system sold consists of the control unit, disposable microkeratomes (sold sterile) for corneal resection, a special microkeratome for epithelial separation, practice microkeratomes (not sold sterile), and interconnection equipment, including hoses, cables, and footpedals.

The HORIZON EPIKERATOME™ microkeratome is a clear, automated, completely assembled, disposable microkeratome. It is made of biocompatible polycarbonate plastic and includes a separator also made of biocompatible polycarbonate plastic.. It is sold sterile and is for single use only. Each

K052891

individual microkeratome is separately packaged in Tyvek, and is sterilized by gamma radiation. The hand ieces for corneal resection use a surgical –grade steel blade instead of a plastic separartor.

The microkeratome itself is powered by two electric motors located in the control unit; motion is transmitted to the keratomes by a flexible mechanical transmission cable. The motors are ULand CE approved. The central unit also supplies the suction. The single cable transmits both the motion to cause the blade(or separator) to oscillate and translate the device axially. As may be seen, there is no electricity transmitted to the keratome units. The microkeratome itself requires no assembly, but the connection to the central unit must be made before the operation. Separate units are available for different resection diameters and depths. The suction tubes are sold sterile one unit for a patient, and are sold with the microkeratomes.

(5) Intended Use

The Horizon Epikeratome ™ is a single-use microkeratome system intended to be used for the separation of the epithelium from the cornea for subsequent surgical procedures on denuded cornea.

(6) Performance data

(1) Non-clinical tests

The Horizon Epikeratome has had electrical safety tests and electromagnetic compatibility tests. Plastic Materials in contact with tissue have been tested for biocompatibility. All motors are UL and CE approved. Blades are surgical-grade stainless steel. Animal studies have been performed to demonstrate the efficacy of the unit. It was compared to the predicate devices in tests with enucleated eyes.

(2) Clinical tests

This device is identical to the predicate device, K981155 (Flapmaker) except that only one cable is used and a special separator is used for epithelial separation. Since there is no change in technology or principles, a clinical test is not required.

(3) Conclusions

The Horizon Epikeratome microkeratome is equivalent in safety and efficacy to the legally-marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 2 3 2006

Hawken Industries Inc.
c/o Dr. George Myers
Medsys Inc.
377 Rt. 17 South
Hasbrouck Heights, NJ 07604

Re: K052891
Trade/Device Name: Horizon Epikeratome Disposable Microkeratome System
Regulation Number: 21 CFR 886.4370
Regulation Name: Keratome
Regulatory Class: Class I
Product Code: HNO
Dated: March 14, 2006
Received: March 15, 2006

Dear Dr. Myers:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for

Malvina Eydelman, M.D.
Director
Division of Ophthalmic and Ear
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name: Horizon Epikeratome

Indications For Use:

The Horizon Epikeratome™ is indicated when it is desired to use a single-use microkeratome system that is intended to be used solely to make anterior lamellar corneal resections of preselected thickness and diameter and for the separation of the epithelium from the cornea for subsequent surgical procedures on denuded cornea.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear,
Nose and Throat Devises

510(k) Number K052891